

EFFICACY REVIEW

Premise Perimeter 0.5 Insecticide, EPA File Symbol 432-RGIN

Premise Perimeter 2 Insecticide, EPA File Symbol 432-RGTO

Premise 75 Insecticide in Water Soluble Packaging, 432-RGIR

Date: 11/02/04

Chemical: Imidacloprid

Premise Perimeter 0.5 Insecticide.....	5.65%
Premise Perimeter 2 Insecticide.....	21.4%
Premise Perimeter 75 Insecticide	
In Water Soluble Packaging.....	75%

Chemical Number: 129099

Purpose: The purpose of this review is to address the deficiencies for product registration and the acceptance of a new use pattern, i.e., Targeted Termite Treatment (T3), for Premise termiticides.

Areas of Consideration: MRID: 45530401. The Efficacy of PREMISE Insecticide Using Minimal Interior Treatment Protocols as Determined in Field Use Research. August 31, 2001. Bayer Corp. Agricultural Division, Research and Development Department. Kansas City, Missouri; Report No. 110952.

MRID: 45779801. Supplement to MRID Number 45530401; Performance Date- The Efficacy of PREMISE Insecticide Using Minimal Interior Treatment Protocols as Determined in Field Use Research. September 30, 2002. Bayer Corp. Agricultural Division, Research and Development Department. Kansas City, Missouri; Report No. 110952-1


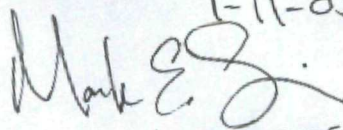
Premise 75 Insecticide in Water Soluble Packets Industrial Retreatment Survey/Trends Analysis MRID 46194361

Performance Data- The Efficacy of PREMISE Insecticide Using Minimal Interior Treatment; Protocols as Determined in Field Use Research; EUP No. 432-EUP-7 Year 1 Results

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Discussion:

MRID: 45530401. The Efficacy of PREMISE Insecticide Using Minimal Interior Treatment Protocols as Determined in Field Use Research. August 31, 2001. Bayer Corp. Agricultural Division, Research and Development Department. Kansas City, Missouri; Report No. 110952.

And

MRID: 45779801. Supplement to MRID Number 45530401; Performance Date- The Efficacy of PREMISE Insecticide Using Minimal Interior Treatment Protocols as Determined in Field Use Research. September 30, 2002. Bayer Corp. Agricultural Division, Research and Development Department. Kansas City, Missouri; Report No. 110952-1

In an efficacy review dated February 6, 2002 (D279042), Joanne Edwards reviewed original research submitted by Bayer Corporation regarding 56 structures containing either active *Reticulitermes* spp (82.1%), *Coptotermes formosanus* (10.7%), or *Heterotermes aureus* (7.1%) infestations. The structures were treated using the 0.05% dilution of a registered Premise product, and differed from the registered directions for use, by replacing "complete" interior applications with "spot" applications. A portion of the recommendations from that review included: the requirement of a full five years of efficacy data and the request that the study be given to the Association of Structural Pest Control Regulatory Officials (ASPCRO).

In an efficacy review dated February 12, 2003 (D286954), Joanne Edwards reviewed a submission containing additional performance data supporting the original study reviewed a year previous, and Bayer's response to the reviews recommendations. Regarding the request for a full five years of efficacy data, Bayer responded that the evaluation of two years of data should be sufficient due to the fact that other termiticides had been accepted using less than five years of data. The reviewer noted that there was no RD policy for accepting less than five years of data, and that data should be available for at least three years of monitoring, since the study was initiated in 1999.

Premise 75 Insecticide in Water Soluble Packet Industrial Retreatment Survey/Trends Analysis

This survey is comprised of data recorded from conventional, perimeter, and spot termiticide applications made between 1996 and 2003 from 34 Pest Management Professional Companies in 23 states. In total, performance data was collected from 9,583 structures used to determine the rate of retreatment for conventional, perimeter, and partial treatments. In addition, a discussion of the observation of the industrial trend to prefer perimeter treatments over conventional treatments was presented.

Performance Data- The Efficacy of PREMISE Insecticide Using Minimal Interior Treatment; Protocols as Determined in Field Use Research; EUP No. 432-EUP-7 Year 1 Results

This interim report is a collaborative data document used to support Bayer's rationale for the EPA to accept the Targeted Interior Treatment (T3) approach for termiticide applications. This report contains data from 115 homes treated under the current EUP (432-EUP-7) program. The two year experimental use permit was obtained in October, 2003, and allows for a maximum of 825 structures to be treated.

In addition, the report contains data discussed within MRID numbers 45530401 and 45779801. These studies contain data from the original 56 homes treated using the Minimal Interior Treatment protocol and were reviewed by Joanne Edwards on February 6, 2002 (D279042) and February 12, 2003 (D286954). Finally, the interim report contains "follow-up" data from 110 homes treated from 1999 through 2002 by pest control companies who adopted the perimeter-style treatments.

Recommendations:

The submitted data do not support product registration or support the acceptance of the new use pattern Targeted Termite Treatment (T3). The following recommendations apply:

1. After careful consideration, the Industrial Retreatment Survey/Trends Analysis has been classified as supplemental information. The Agency has decided that this survey, regardless of the amount of data it contains, is not the equivalent to a scientific study, and therefore cannot be considered as such. The following factors were used to make this decision.
 - a. Though the survey contained data from a significant number of structures, there were no positive or negative controls used. Controls are a necessity to establish a point of comparison.
 - b. Unlike a scientific study, which is carried out in a controlled environment, the survey contained too many questionable variables. Because this survey contained data from many different companies within multiple states, the necessary information had to be shifted from individual to individual before ever being received by a Bayer representative to be manually entered into the database. This high level of data "transferal" leads to an extremely high possibility of error. To assume the overall accuracy of the survey as a whole, the Agency would therefore need to entrust an extremely high level of accuracy, responsibility, and integrity not only to each of the Bayer representatives, but also to each of the 34 Pest Management Professional companies and to every single technician that serviced the 11,685 structures.
 - c. To be able to determine the rate of retreatment for the survey, the following definitions were established: 1. conventional treatments were any application using more than 0.6 gallons/linear foot 2. perimeter treatments were any

application using between 0.3 and 0.6 gallons/linear foot 3. partial treatments were any application using less than 0.3 gallons/linear foot.

It would be impossible to obtain an accurate number of conventional, perimeter, and partial treatments if the counts were solely based on volumetric measurements. The amount of chemical used per application does not specify the quantity, if any, were applied indoors. Essentially what this survey concluded was that when structures were treated with over 0.6 gallons/linear foot, the retreatment rate was 0.68%. Applications using between 0.3 and 0.6 gallons/linear foot had a retreatment rate of 1.24%, while applications using less than 0.3 gallons/linear foot had a retreatment rate of 1.95%.

- d. An additional factor which could lead to an inaccurate retreatment rate was the fact that companies relied on homeowner call-backs for retreatments. It is a large assumption that if there was no call-back, the structure is free of termite infestation. Possible factors that should be taken into account include: 1. there are visible active termite infestation sites within the home, however the homeowner is unaware of what signs to look for 2. there are active infestation sites within the home that are not visible 3. the homeowner has broken the contractual agreement and has called upon the services of another company to solve their termite infestation problem.
- e. When discussing the general application trends between the years of 1997 and 2002 for Pest Management Professionals, it was stated that a greater percentage of perimeter treatments were applied toward the end of the five year period. Because the majority of retreatments occur following a few years after the initial application, it can be assumed that the rate of retreatment for perimeter treatments might be substantially higher.

- 2. The data reviewed within the interim report was deemed unsatisfactory. The area of significance was the data demonstrating the status of the current EUP. However, because data from a 110 home survey and data from the original 56 home study were combined, information from the current EUP were indistinguishable. In a Bayer email dated October 28, 2004, it was stated that by November 8, 2004, Bayer will report one year data on 106 homes from the current EUP. This information should be submitted to the Agency for review, free of any other additional data from past research or survey.

Premise / Termidor Data Comparison- It should be noted that the Termidor SC & 80 WG products submitted the following substantial supportive data before being approved for the new use pattern.

- 1. USDA Forest Service Ground Board/Concrete Slab Studies
- 2. Soil Residue Data
- 3. Completed EUP
- 4. ASPCRO consultation on protocol
- 5. Trophallaxis